REMARKS

Claims 54-71 are canceled without prejudice or disclaimer. Claims 72-90 are added, and therefore claims 72-90 are pending in the present application. Claims 72-90 are supported by claims 54-71. Claim 90 is further supported by the feed compositions described on page 36 of the specification.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 54-65 and 70 under 35 U.S.C. 112

Claims 54-65 and 70, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

It is well settled "[t]he test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter...." *In re Kaslow*, 217 USPQ 1089, 1096 (Fed. Cir. 1983).

As set forth in Federal Circuit decisions, a specification complies with the written description requirement if it provides "a precise definition, such as by structure, formula, chemical name, or physical properties of the claimed subject matter sufficient to distinguish it from other materials." See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002).

The xylanases for use in the animal feed compositions of the present invention are precisely defined by structure and physical properties. Moreover, Applicants have identified numerous sources for the xylanases used in the present invention, including *Byssochlamus*, *Chaetomium*, *Humicola*, *Malbranchea*, *Mucor*, *Myceliophthora*, *Paecilomyces*, *Talaromyces*, *Thermoascus*, *Thermomyces* and *Thielavia*. Applicants therefore submit that the specification reasonable conveys to one of ordinary skill in the art that Applicants had possession of the invention at the time the application was filed.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

II. Th R jecti n of Claims 54-70 under 35 U.S.C. 102 and 103

Claims 54-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Lischnig et al. (Biotechnology Letters, Vol. 15, No. 4, pp. 411-414 (1993)), or Gomes et al. (Appl. Microbiol. Biotechnol., Vol. 39, pp. 700-707 (1993)) or Alam et al. (Enzyme Microb. Technol., Vol. 16, pp. 298-302 (1994)), or Wizani et al. (US 5,183,753, 2-2-1993), or in the alternative, under 35 U.S.C. 103 as obvious over Lischnig et al. or Gomes et al. or Alam et al. and Haarasilta et al. (US 5,314,692, 5-24-1994), Hazlewood et al. (WO 93/25693, 12-23-1993). This rejection is respectfully traversed.

Lischnig et al. disclose an endo-beta-xylanase derived from *Thermomyces lanuginosa*, DSM 5026, which has a pH optimum of 6.5 and is active at pH values up to 9.0, and has a residual activity of at least about 80% after incubation at 70°C for 10 minutes at pH 6-9. Lischnig et al. also disclose that the xylanase shows sufficient thermostability for use as a bleaching aid in the pulp and paper industry.

Gomes et al. disclose a xylanase derived from a *Thermomyces lanuginosa* strain, which was deposited at Deutsche Sammlung von Mikroorganismen und Zellkulturen under the number DSM 5826. Gomes et al. further disclose that the xylanase was almost thermostable (91-92%) at pH 6.6 and 9.0 after 41 hours preincubation at 55°C and lost only 20-33% activity after 188 hours. Gomes et al. further disclose that the xylanase is extremely valuable in the bleaching of paper pulp.

Wizani et al. disclose a xylanase derived from the same *Thermomyces lanuginosa* strain as the one in Gomes et al., namely DSM 5826. Wizani et al. further disclose that this xylanase is cellulase-free.

However, neither Lischnig et al., Gomes et al., nor Wizani et al. disclose animal feed compositions comprising a thermostable xylanase of Family 11, as claimed herein.

Alam et al. disclose thermostable xylanases derived from *Thermomyces lanuginosus* and *Thermoascus aurantiacus*. These xylanases are dislosed as holding a great potential for application in pulp, paper, and jute fiber processing industries. In the summary of Alam et al. (lines 3-4) it is further disclosed that *T. lanuginosus* produced cellulase-free xylanase, and *T. aurantiacus* produced only a small amount of cellulase in addition to xylanase. Alam et al. do not in any way whatsoever teach or suggest the use of the disclosed *Thermomyces* xylanases in animal feed applications. The only disclosure relating to animal feed in Alam et al. is in the introduction where Alam et al. state that in some cases, there is a synergistic effect between xylanases (in general) and cellulase, e.g. maximum conversion of lignocellulose into liquid

feedstocks and increasing the digestibility of animal feed. However, this statement clearly does not apply to the *Thermomyces* xylanases since they are either cellulase-free or have only a small amount of cellulase, and furthermore the only disclosure of utilities of the *Thermomyces* xylanases in Alam et al. is biopulping and jute fiber processing (see page 301, left hand column, last paragraph). Thus, Alam et al. do not disclose the use of *Thermomyces* xylanases in animal feed applications.

Significantly, none of the cited references teach or suggest the use of thermostable xylanases in animal feed compositions, or that there would be any advantage to using a thermostable xylanase over a thermolabile xylanase in animal feed.

Moreover, Applicants have demonstrated that the use of thermostable xylanases of Family 11 according to the present invention significantly improves feed utilization as compared to other xylanases. For example, in Example 8, Applicants have compared the digestability of animal feeds comprising a thermostable xylanase of Family 11 ("A" and "B") vs. the digestability of an animal feed comprising Bio-Feed Plus ("C"), a commercially-available xylanase preparation derived from *Humicola insolens*. The results show that the use of Bio-Feed Plus at a dose of 400 FXU/kg gave a % fat digestion of 72.4, whereas the animal feeds comprising a xylanase of the present invention gave a % fat digestion in the range of 72.1-74.3 even though the xylanase was dosed at 100 or 200 FXU/kg (one quarter or one-half, respectively, of the Bio-Feed Plus). These results demonstrate that animal feeds comprising a thermostable xylanase of Family 11 have a significantly better digestability than an animal feed comprising Bio-Feed Plus. Since the demonstrated superior property is not predicted by the prior art, these results are surprising and unexpected and the showing overcomes any assertion of obviousness based on the cited art.

Applicants also submit a Declaration under 37 C.F.R. 1.132 of Dan Petterson, which describes experiments that were performed to measure apparent metabolisable energy (AME). Specifically, broilers were fed an animal feed composition with and without a xylanase. In one animal feed, the xylanase was a *Thermomyces lanuginosus* xylanase having an amino acid sequence of SEQ ID NO: 2 of the present invention and in another, the xylanase was an *Aspergillus aculateus* xylanase. In his declaration, Dr. Petterson states that "The results demonstrate that animal feeds comprising the *Thermomyces lanuginosus* xylanase results in significantly better feed utilization than animal feed compositions comprising the *Aspergillus aculateus* xylanase." In addition, he states that the results are "surprising and unexpected."

For the foregoing reasons, Applicants submit that the claims overcome these rejections under 35 U.S.C. 102/103. Applicants respectfully request reconsideration and withdrawal of the rejections.

III. The Rejection of Claims 54-70 under the Doctrine of Obviousness-Type Double Patenting

Claims 54-70 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,245,546.

Applicants will submit a terminal disclaimer upon an indication of allowable subject matter.

IV. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: September 4, 2003

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Attorney Docket No.: 4324.224-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Hansen et al. Confirmation No: 2312

Serial No.: 09/467,368 Group Art Unit: 1652

Filed: December 21, 1999 Examiner: Rao, M

For: Animal Feed Additives

DECLARATION UNDER 37 C.F.R. 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dan Robert Pettersson, do hereby state and declare that

1. I received a Master of Science in Agriculture degree (animal nutrition and management) in 1983 at the Swedish University of Agricultural Sciences. I began my Ph.D. studies in 1984 with an Agr.D. exam in 1988, at the same university. Thesis title "Composition and productive value for broiler chickens of wheat, triticale and rye". In 1993 I obtained a degree as Associate professor in Food Science at the department of Food Science (Swedish University of Agricultural Sciences) where I worked as a scientist until 1995. Since November 1995 I have been employed by Novozymes A/S (previously a part of Novo Nordisk A/S), the owner of the above-captioned application. From November 1995 I worked in Enzyme Business Marketing. I later moved to Research (1996 – 2000) as a Research Scientist, and from 2000 until the present, I have been a Technology Manager. During my years in research I have been involved in application studies of different enzymes for animal feed.

2. The following experiments were carried out under my direction and supervision. A trial to measure apparent metabolisable energy (AME) was conducted in the following way. Day-old broilers were raised on a commercial starter diet to day 21 of age and birds were then transferred to wire mesh cages with 8 birds in each cage and with 8 replications (cages) used for each dietary treatment. The first four days served as an adaptation period for the diet used (Table 1) and for the last four days excreta were collected daily, dried overnight in a forced-air oven at 80°C and pooled for determination of gross energy. The amount of feed consumed during the excreta collection period was recorded. AME was calculated as the amount of gross energy consumed from diet minus gross energy excreted via excreta (faeces+urine) divided by feed intake to obtain the energy retention as MJ/kg diet. The AME value of the major dietary ingredient (the wheat) was obtained using a pre-determined AME value (20.1 MJ/kg DM) for casein. The calculation of the AME of the cereal was follows:

AMEgrain = (AMEdiet - AMEcasein x dry casein level)/dry grain level.

This is a measurement of the amount of energy that the cereal can provide for growth and maintenance of the animal. Where digesta was required for viscosity measurements, the birds were killed on completion of the AME bioassay and the contents of the duodenum, jejunum, ileum (from Meckel's diverticulum to 4 cm above the ileo-caecal junction) and caeca were collected in pre-weighed containers and fresh weights recorded. The supernatants and the pellets were immediately separated by centrifugation (12,000 g, 15 min). Viscosity measurements on the supernatants were carried out using a Brookfield DVIII model viscometer at 25°C with a CP40 cone and shear rate of 5-500 s-1.

Table 1: Feed composition of the experimental diet

Ingredient	g/kg
Wheat (Currawong)	784
Casein	149
Dicalcium phosphate	19.6
Calcium carbonate	10.8
DL-Methionine	6.8
Pre-mix	4.9
NaCl	2.9
Choline chloride (50%)	2
Celite	20

One xylanase was a *Thermomyces lanuginosus* xylanase having an amino acid sequence of SEQ ID NO: 2 of the present application, and the other was a xylanase of Family 10 xylanase derived from *Aspergillus aculeatus* (xylanase 2 of WO 94/21785). The enzymes were dosed at 200 FXU/kg feed composition.

The results of the trial are summarized in the following tables:

Enzyme	AME (MJ/kg)	FCR (feed:gain)	Excreta moisture (%)
No Enzyme	13.65	2.16	77.1
Enzyme derived from			
Thermomyces lanuginosus	14.50	1.97	73.4
Aspergillus aculeatus	14.15	2.02	75.0

	Viscocity, cP		
Enzyme	Duodenum	Jejunum	Ileum
No Enzyme	3.28	7.99	23.31
Enzyme derived from			
Thermomyces lanuginosus	2.16	4.08	6.77
Aspergillus aculeatus	2.31	3.32	7.75

4. The results demonstrate that animal feeds comprising the *Thermomyces lanuginosus* xylanase results in significantly better feed utilization than animal feed compositions comprising the *Aspergillus aculeatus* xylanase. These results are surprising and unexpected.

5. The undersigned declarant declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize any patent issuing thereon.

Signed this 4 day
of September 2003

Dan Robert Pettersson